

Rec'd PTO 06 NOV 2001
U91830968

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carcagno *et al.*

Appl. No. 09/830,968

Filed: May 3, 2001

For: **Methods for the Massive Culture of
Cells Producing Recombinant
Human Erythropoietin**

#6

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1909.0040002/JAG/CMB

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AT3, AR4, AS4 and AT4 cited on Form PTO 1449:

Documents AT3, AR4, AS4 and AT4 are in the French language. No English translations are readily available. These documents appear to show evidence of a substance isolated from blood capable of regulating hematopoiesis.

Document AT11 is in a foreign language. An English language abstract is on the first page of this document.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 09/830,967, filed May 3, 2001, submitted herewith as Document AS17; and

U.S. Patent Application No. 09/830,964, filed May 3, 2001, submitted herewith as Document AT17.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

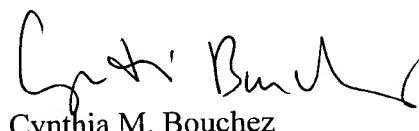
This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Cynthia M. Bouchez

Agent for Applicants

Registration No. 47,438

Date: November 6, 2001

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

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| FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT | | | ATTY. DOCKET NO. 1909.0040002/JAG/CMB | APPLICATION NO. 09/830,968 | |
| | | | APPLICANT Carcagno <i>et al.</i> | | |
| | | | FILING DATE May 3, 2001 | GROUP <i>To Be Assigned</i> | |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE |
|------------------|-----|-----------------|------------|---------------------------------|-------|-----------|-------------|
| | AA1 | 4,667,016 | 05/19/1987 | Lai <i>et al.</i> | 530 | 397 | 06/20/1985 |
| | AB1 | 4,667,195 | 06/30/1987 | Hewick <i>et al.</i> | 530 | 397 | 01/11/1985 |
| | AC1 | 4,703,008 | 10/27/1987 | Lin | 435 | 240.2 | 11/30/1984 |
| | AD1 | 4,806,524 | 02/21/1989 | Kawaguchi <i>et al.</i> | 514 | 8 | 10/03/1985 |
| | AE1 | 5,010,002 | 04/23/1991 | Levinson <i>et al.</i> | 435 | 69.2 | 03/22/1990 |
| | AF1 | 5,547,933 | 08/20/1996 | Lin | 514 | 8 | 06/07/1995 |
| | AG1 | 5,618,698 | 04/08/1997 | Lin | 435 | 69.4 | 06/06/1995 |
| | AH1 | 5,688,679 | 11/18/1997 | Powell | 435 | 240.2 | 10/06/1993 |
| | AJ1 | 5,756,349 | 05/26/1998 | Lin | 435 | 325 | 06/06/1995 |
| | AK1 | 5,783,559 | 07/21/1998 | Florin-Robertsson <i>et al.</i> | 514 | 12 | 01/10/1994 |

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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
|------------------|-----|-----------------|------------|----------|-------|-----------|-------------|
| | AL1 | WO 86/03520 ✓ | 06/19/1986 | WIPO/PCT | | | Yes No |
| | AM1 | WO 98/00530 ✓ | 01/08/1998 | WIPO/PCT | | | Yes No |
| | AN1 | WO 00/27419 ✓ | 05/18/2000 | WIPO/PCT | | | Yes No |
| | AO1 | WO 00/27869 ✓ | 05/18/2000 | WIPO/PCT | | | Yes No |
| | AP1 | WO 00/27997 | 05/18/2000 | WIPO/PCT | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| AR | 1 | Andersen, D.C. and Goochee, C.F., "The effect of cell-culture conditions on the oligosaccharide structures of secreted glycoprotein," <i>Curr. Op. Biotech.</i> 5:546-549, Current Biology Ltd. (1994). |
| AS | 1 | Bondurant, M.C. and Koury, M.J., "Anemia Induces Accumulation of Erythropoietin mRNA in the Kidney and Liver," <i>Mol. Cell. Biol.</i> 6:2731-3, American Society for Microbiology (1986). |
| AT | 1 | Borsook, H., <i>et al.</i> , "Polycythemic Response in Normal Adult Rats to a Nonprotein Plasma Extract from Anemic Rabbits," <i>Blood</i> 9:734-742, Grune and Stratton, Inc. (1954). |

| EXAMINER | DATE CONSIDERED |
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
| | AL2 | WO 00/28066 ✓ | 05/18/2000 | WIPO/PCT | | | Yes No |
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| AR | 2 | Bowie, J.U., et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions," <i>Science</i> 247:1306-1310, American Association for the Advancement of Science (1990). |
| AS | 2 | Brown, P.R. and Krstulovic, A.M., "Practical Aspects of Reverse-Phase Liquid Chromatography Applied to Biochemical and Biomedical Research," <i>Anal. Biochem.</i> 99:1-21, Academic Press, Inc. (1979). |
| AT | 2 | Burg, J., et al., "Human erythropoietin recombinant production by fermentation and protein purification using a series of chromatographic steps," <i>Chem. Abstracts</i> 126:315 Abstract No. 57095j, American Chemical Society (1997). |

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| OTHER (Including Author, Title, Date, Pertinent Pages, etc.) | | | | | | | |
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| | AR | 3 | Busuttil, R.W., et al., "The Cytological Localization of Erythropoietin in the Human Kidney Using the Fluorescent Antibody Technique," Proc. Soc. Exp. Biol. Med. 137:327-330, Academic Press, Inc. (1971). | | | | |
| | AS | 3 | Busuttil, R.W., et al., "Localization of Erythropoietin in the Glomerulus of the Hypoxic Dog Kidney Using a Fluorescent Antibody Technique," Acta Haemat. 47:238-242, S. Karger (1972). | | | | |
| | AT | 3 | Carnot, M.P. and Deflandre, C., "Sur l'activité hémopoïétique du sérum au cours de la régénération du sang," C.R. Acad. Sci. 143:384-386, (1906). | | | | |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | 4 | Carnot, M.P. and Deflandre, C., "Sur l'activité hémopoïétique des différents organes au cours de la régénération du sang," <i>C.R. Acad. Sci.</i> 143:432-435 (1906). |
| | AS | 4 | Carnot, M.P., "Sur le Mécanisme de L'hyperglobulie Provoquée par le Sérum D'animaux en Rénovation Sanguine," <i>C.R.H. Sean. Mem. Soc. Biol.</i> 111:344-346, Libraires de L'Académie de Médecine (1906). |
| | AT | 4 | Carnot, M.P., "Sur L'activité Cytopoïétique du Sang et des Organes Régénérés au Cours des Régénérations Viscérales," <i>C.R.H. Sean. Mem. Soc. Biol.</i> 111:463-465, Libraires de L'Académie de Médecine (1906). |

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|----|---|---|
| AR | 5 | Caro, J. and Erslev, A.J., "Biologic and immunologic erythropoietin in extracts from hypoxic whole rat kidneys and in their glomerular and tubular fractions," <i>J. Lab. Clin. Med</i> 103:922-931, C.V. Mosby Company (1984). |
| AS | 5 | Caro, J., et al., "Erythropoietin Production by an Established Kidney Proximal Tubule Cell Line (LLCPK ₁)," <i>Exp. Hematol</i> 12:357, Springer-Verlag (1984). |
| AT | 5 | Caro, J., et al., "Erythropoietin in liver tissue extracts and in liver perfusates from hypoxic rats," <i>Am. J. Physiol.</i> 244:E431-E434, American Physiological Society (1983). |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | 6 | Dinkelaar, R.B., et al.. "Metabolic Studies on Erythropoietin (Ep): II. The Role of Liver and Kidney in the Metabolism of Ep," <i>Exp. Hematol.</i> 9:796-803, Allen Press, Inc. (1981). |
| | AS | 6 | Dornfest, B.S., et al., "Hepatic production of erythropoietin in a phenylhydrazine-induced compensated hemolytic state in the rat," <i>J. Lab. Clin. Med.</i> 102:274-85, C.V. Mosby Company (1983). |
| | AT | 6 | Dornfest, B.S., et al., "Recovery of an Erythropoietic Inducing Factor from the Regenerating Rat Liver," <i>Ann. Clin. Lab. Sci.</i> 11:37-46, Institute for Clinical Science (1981). |

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AR | Z | Erslev, A., "Humoral Regulation of Red Cell Production," <i>Blood</i> 8:349-357, Grune and Stratton, Inc. (1953). |
| | AS | Z | Erslev, A.J., "In Vitro Production of Erythropoietin by Kidneys Perfused With a Serum-free Solution," <i>Blood</i> 44:77-85, Grune and Stratton, Inc. (1974). |
| | AT | Z | Erslev, A.J. and Caro, J., "Physiologic and Molecular Biology of Erythropoietin," <i>Med. Oncol. Tumor Pharmacother.</i> 3:159-164, Pergamon Press (1986). |

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| AR | <u>8</u> | Eschbach, J.W., et al., "Correction of the Anemia of End-Stage Renal Disease with Recombinant Human Erythropoietin," <i>New Eng. J. Med.</i> 316:73-78, Massachusetts Medical Society (1987). |
| AS | <u>8</u> | Fisher, J.W. and Birdwell, B.J., "The Production of an Erythropoietic Factor by the In Situ Perfused Kidney," <i>Acta Haemat.</i> 26:224-232, S. Karger (1961). |
| AT | <u>8</u> | Fisher, J.W., et al., "Localization of Erythropoietin in Glomeruli of Sheep Kidney by Fluorescent Antibody Technique," <i>Nature</i> 205:611-612, Macmillan Magazines Ltd. (1965). |

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